

**REMARKS**

Reconsideration in view of the foregoing amendments and following remarks is respectfully requested.

Amendments to the title, specification and abstract are editorial in nature and have been made to correct errors in spelling, grammar, and punctuation; to provide consistency in terminology throughout the entire application; and to otherwise eliminate informalities existing in the original description. No new matter has been added. Paragraph numbers have been added to the "substitute" specification, but are not indicated on the marked-up copy.

A parts list is now being submitted.

**FIGS. 15 and 16** are being deleted.


Amendments to the claims are editorial in nature, and no new matter has been added. Where applicable, subparagraphs in the claims have now been identified with lower case letters.

If there are any further issues yet to be resolved to advance the prosecution of this patent application to issue, the Examiner is requested to telephone the undersigned counsel.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,

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Attachments:   Substitute specification and abstract  
                  Marked-up copy of original specification  
                  and abstract  
                  New Parts List

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[Attorney Docket No. 2856-06US02]

PROTECTIVE SYSTEM OR APPARATUS INCLUDING  
A GUIDEWIRE HAVING DEPLOYABLE  
A SHEATHLESS [PROTECTIVE] FILTER  
AND METHOD UTILIZING SAME

RELATED APPLICATION

5 This application claims the benefit of U.S. Provisional Application No. 60/437,166, filed December 30, 2002, incorporated herein in its entirety by reference.

FIELD OF THE INVENTION

The present invention relates generally to the field of vascular medical devices. More  
10 specifically, the present invention relates to a [guidewire] or apparatus  
procedures that <sup>includes</sup> produce a deployable <sup>that is sheathless</sup> [convey] filter [without the use of a sheath].

BACKGROUND OF THE INVENTION

Arterial disease involves damage that happens to the arteries in the body. Diseased  
15 <sup>arteries</sup> [vessels] can become plugged with thrombus, plaque, or grumous material that may ultimately  
lead to a condition known as ischemia. Ischemia refers to a substantial reduction or loss of blood  
flow to the heart muscle or any other tissue that is being supplied by the artery and can lead to  
permanent damage of the affected region. While arterial disease is most commonly associated  
with the formation of hard plaque and coronary artery disease in the heart, similar damage can  
20 happen to many other vessels in the body, such as the peripheral vessels and cerebral vessels, due  
to the build up of hard plaque or softer thrombus or grumous material within the lumen of an  
artery or vein.

A variety of vascular medical devices and procedures have been developed to treat diseased vessels. The current standard procedures include bypass surgery (where a new blood vessel is grafted around <sup>a</sup> ~~the~~ narrowed or blocked artery) and several different types of non-surgical interventional vascular medical procedures, including angioplasty (where a balloon on  
5 a catheter is inflated inside <sup>a</sup> ~~the~~ narrowed or blocked portion of <sup>an</sup> ~~the~~ artery in an attempt to push back ~~the~~ plaque or thrombotic material), stenting (where a metal mesh tube is expanded against <sup>a</sup> ~~the~~ narrowed or blocked portion of <sup>an</sup> ~~the~~ artery to hold back ~~the~~ plaque or thrombotic material), and debulking techniques in the form of atherectomy (where some type of high speed or high power mechanism is used to dislodge ~~the~~ hardened plaque) or thrombectomy (where some type of  
10 mechanism or infused fluid is used to dislodge grumous <sup>or</sup> thrombotic material). In each of these <sup>interventional</sup> vascular medical procedures, a very flexible guidewire is routed through the patient's vascular system to a desired treatment location and then a catheter that includes a device on the distal end appropriate for the given procedure is tracked along the guidewire to the treatment location.

Although interventional vascular procedures avoid many of the complications involved in  
15 surgery, there is a possibility of complications if some of the plaque, thrombus or other material breaks free and flows downstream in the artery <sup>or other vessel</sup> potentially causing a stroke, a myocardial infarction (heart attack), or other tissue death. One solution to this potential complication is to use some kind of occlusive device or filtering device to block or screen the blood flowing downstream of the treatment location.

20 The use of a protective device in the form of an occlusive device or filtering device as part of a vascular procedure is becoming more common in debulking procedures performed on heart bypass vessels. Most heart bypass vessels are harvested and transplanted from the

saphenous vein located along the inside of the patient's leg. The saphenous vein is a long, straight vein that has a capacity more than adequate to support the blood flow needs of the heart.

Once transplanted, the saphenous vein is subject to ~~arterial disease caused by~~ <sup>a buildup of</sup> plaque or thrombotic materials ~~that build up~~ in the grafted arterial lumen. Unfortunately, the standard

5 interventional vascular treatments for debulking are only moderately successful when employed to treat saphenous vein coronary bypass grafts. The complication rate for a standard balloon angioplasty procedure in a saphenous vein coronary bypass graft is higher than in a native vessel with the complications including embolization, "no-reflow" phenomena, and procedural related myocardial infarction. Athero<sup>o</sup>ectomy methods including directional, rotational, and laser devices

10 are also associated with a high degree of embolization resulting in a greater likelihood of infarction. The use of stents for saphenous vein coronary bypass grafts has produced mixed results. Stents provide for less restenosis, but they do not eliminate the risk of embolization and infarction <sup>incurred by standard balloon angioplasty</sup>

In order to overcome the shortcomings of these standard non-surgical interventional  
15 treatments in treating saphenous vein coronary bypass graft occlusion, embolic protection methods utilizing a protective device distal to the lesion have been developed. The protective device is typically a filter or a balloon. Use of a protective device in conjunction with an athero<sup>o</sup>ectomy or thrombectomy device is intended to prevent emboli from migrating beyond the protective device <sup>to</sup> and allow the embolic particles to be removed, thereby subsequently reducing  
20 the risk of myocardial infarction. When the protective device is a balloon, the balloon is inserted and inflated at a point distal to the treatment site or lesion site. Therapy is then performed at the ~~treatment~~ site and the balloon acts to block all blood flow, which prevents emboli from traveling

beyond the balloon. Following treatment, some form of particle removal device must be used to remove the dislodged emboli prior to balloon deflation. U.S. Patent No. 5,843,022 uses a balloon to occlude the vessel distal to a lesion or blockage site. The occlusion is treated with a high pressure water jet, and the fluid and entrained emboli are subsequently removed via an extraction tube. U.S. Patent No. 6,135,991 describes the use of a balloon to occlude the vessel allowing blood flow and pressure to prevent the migration of emboli proximally from the treatment device. While effective as a protective device, balloons may result in damaged tissue due to lack of blood flow downstream of the treatment area due to the time required to inflate and deflate the balloon.

To overcome this disadvantage, most development in relation to occlusive devices has focused on devices that screen the blood through a filter arrangement. An early arterial filtering system utilizing a balloon catheter with a strainer device is described in U.S. Patent No. 4,873,978. The device is inserted into a vessel downstream of the treatment site. The strainer responds to actuation of a separately introduced control cable to open and close a plurality of tines capable of retaining dislodged particles. After treatment, the strainer is collapsed and the entrapped emboli are removed from the body. The additional wire, however, creates additional complexity for the user.

More recently, filter designs have been deployed through the use of a single guidewire in which the filter device is transported to the deployment area within a sheath or catheter. Typical filters have either an umbrella shape to capture emboli or a tube shape in which the proximal end contains larger openings than the distal end so as to allow the blood and debris to enter the filter. The filter thus presents an operational face to the flow of blood within the vessel as provided by

the distal end of the tubular filter that is concave in orientation. Particles are captured within the concave face of the filter and are then retracted out of the vessel when the entire device is removed from the body.

a filter

One of the challenges regarding filters is the manner in which ~~it~~ is transported to and  
5 from the area of interest. U.S. Patents Nos. 6,042,598, 6,361,546, 6,371,970, 6,371,971 and  
6,383,206 describe various examples of filter arrangements that are to be deployed through a  
sheath, while U.S. Patents Nos. 6,080,170, 6,171,328, 6,203,561, 6,364,895, and 6,325,815  
describe filters that are deployed by <sup>a</sup> catheter. For example, U.S. Patent No. 6,371,971 describes  
a blood filter positioned by way of a single guidewire, covered by a sheath for advancement  
10 through <sup>a vessel</sup> the channel. The sheath compresses ~~the~~ struts of the filter while in transit. An  
interventional procedure requires deployment of the sheath along a guidewire down stream of the  
vascular occlusion. The sheath is retracted and the filter expands to a predetermined size. The  
filter is retrieved after the procedure by deploying the sheath back down the guidewire, capturing  
the filter and removing the system from the patient.

15 The disadvantage associated with this type of filter is the added thickness of the device  
due to the use of a sheath to deploy the filter. Typical sheath diameters exceed 0.040 inches.  
Insertion of the sheath can damage the vessel during routing and deployment to the occluded  
area and during removal. Moreover, the bulky sheath protecting the filter can hamper the debris  
removal or cause further embolization.

20 There is a need then for a protective device capable of embolization protection for  
vascular and arterial procedures without the design limitations of the existing approaches.  
Occlusive balloons can remain in place too long <sup>thus</sup> increasing the risk of vessel damage

downstream of the occlusion. Protective filters avoid this problem but suffer from complicated deployment and retraction schemes. Moreover, existing filters are limited in range due to the filter framework, which also may result in vessel damage. It would be desirable to provide an occlusive filter device <sup>that is along a single guidewire</sup> easily deployable without a large diameter sheath ~~along a single~~ <sup>and</sup> guidewire ~~that~~ reduces the potential for vessel damage.

### SUMMARY OF THE INVENTION

The present invention is a ~~guidewire~~ <sup>or apparatus</sup> protective system <sup>the tubular</sup> for use in vascular procedures comprising a tubular guidewire, a control cable disposed within the lumen of ~~the~~ <sup>the</sup> guidewire; and a

10 sheathless ~~convex protective~~ <sup>tubular sheathless</sup> filter distally coupled to the control cable and proximally coupled to the guidewire. The filter radially expands as the distal end of the <sup>sheathless</sup> filter is drawn toward the <sup>of the sheathless filter</sup> proximal end in response to displacement of the control cable relative to the tubular guidewire.

The primary filter action is provided by the <sup>proximal</sup> outer <sup>sheathless</sup> convex surface of the filter, which is the first <sup>to come</sup> surface in contact with the flow of blood within ~~the~~ <sup>a blood</sup> vessel.

15 In a preferred embodiment, the <sup>sheathless</sup> filter is comprised of a braided ~~Nitinol wire~~ <sup>skeleton</sup> ~~framework~~ <sup>framework</sup> in the form of a tube to which ~~other fibers~~ <sup>woven strands</sup> are ~~woven~~ <sup>applied</sup> to create a filter mesh. In one

embodiment, the ~~other fibers~~ <sup>woven strands</sup> are multifilament polymer fibers. In an alternate embodiment, the ~~other fibers~~ <sup>woven strands</sup> are ~~other~~ <sup>The distal end of the</sup> Nitinol wires of different diameters. ~~The~~ <sup>The</sup> control cable is attached to the distal end of the ~~tubular mesh~~ <sup>sheathless</sup> filter <sup>and the</sup>. The proximal end of the control cable extends beyond the

20 proximal end of the tubular guidewire for access. Pulling the proximal end of the control cable draws the distal end of the <sup>sheathless</sup> ~~tubular mesh~~ <sup>of the sheathless filter</sup> filter towards the proximal end which is attached to the <sup>tubular</sup> ~~guidewire~~ <sup>sheathless</sup>. The filter expands radially until it either fills the <sup>blood</sup> vessel or reaches a maximum

expansion point at which filter openings are still smaller than the smallest expected particle size of clinical significance. The filter may be locked in place to prevent premature closure of the filter. In one embodiment, the filter is provided with a radiopaque marker that provides an indication of the position and deployment state of the filter under fluoroscopy.

5 Unlike existing filters that have a concave operational surface, the proximal ~~face~~ <sup>exterior surface</sup> of the deployed ~~filter~~ <sup>sheathless</sup> filter of the present invention has a convex shape that provides a first ~~filter~~ <sup>or primary</sup> filter surface. Particle removal from the convex ~~surface~~ <sup>filter</sup> is preferably accomplished in conjunction with a catheter-based aspiration device, such as a ~~thrombectomy~~ <sup>t</sup> ~~device~~ <sup>d</sup>, U.S. Patent No. 5,370,609, commonly referred to as an AngioJet<sup>®</sup>. The use of an aspiration device enables removal of the majority of particles trapped by the convex ~~face~~ <sup>filter surface</sup> prior to retraction of the ~~filter~~ <sup>sheathless</sup> filter through an evacuation lumen. Should debris escape the mesh of the convex ~~face~~ <sup>proximal</sup> ~~surface~~ <sup>primary filter</sup>, the interior distal ~~face~~ <sup>surface</sup> of the filter creates a ~~second~~ <sup>secondary</sup> concave ~~back~~ <sup>filter</sup> filter surface which also traps debris. Extraction requires reducing the ~~filter~~ <sup>sheathless</sup> filter diameter by retracting the ~~Nitinol~~ <sup>sheathless</sup> control cable. The collapsed ~~tubular~~ <sup>sheathless</sup> filter holds debris trapped by the secondary filter surface during the removal process.

15 In a preferred embodiment, the tubular guidewire is advanced over the control cable in a slidable fashion. A short ~~intermediate~~ <sup>intermediate</sup> tube, disposed ~~between~~ <sup>between</sup> the control cable and the ~~guidewire~~ <sup>tubular</sup> at the proximal end of the ~~guidewire~~ <sup>tubular</sup>, provides resistance to the control cable movement. The resistive force maintains the position of the control cable relative ~~to~~ <sup>to</sup> the ~~guidewire~~ <sup>tubular</sup> during a procedure. Alternatively, the ~~filter~~ <sup>sheathless</sup> filter may be locked into position either by a torque device ~~tightened over the tubular guidewire~~ <sup>by a clamp</sup>, or by an interference fit ~~of a feature on~~ <sup>created by a projection on</sup> the control cable mating with the inner diameter ~~of the tubular guidewire~~ <sup>surface</sup>. At the distal end of the control cable, radial expansion of the ~~filter~~ <sup>sheathless</sup> filter is limited to maintain appropriate maximum allowable mesh



spacing. A stop is crimped on to the control cable beyond the distal end of the tubular guidewire. The ~~crimp~~ <sup>stop</sup> blocks control cable ~~advancement~~ <sup>retraction</sup> into the tubular guidewire at the acceptable limit of deployment. Alternatively, the location at which the proximal end of the ~~filter~~ <sup>sheathless</sup> is joined to the tubular guidewire can be used to control the extent of deployment.

5 In one embodiment for coronary vascular procedures, the tubular guidewire ~~assembly~~ preferably has an effective length of ~~190~~ <sup>180</sup> cm. The diameter of the ~~sheath~~ <sup>outer tubular guidewire</sup> would be 0.014 inches. Starting profile of the ~~filter~~ <sup>sheathless</sup> is 0.030 inches and fully expanded profile would be 0.3 inches. There is no deployment delay as with inflating a balloon. Deployment is immediate upon activation of the control cable. This embodiment in combination with an aspiration debris removal device is particularly adapted to provide distal embolization protection in debulking vascular interventional procedures, such as those involving a blocked saphenous vein coronary bypass graft. The aspiration debris removal device removes the majority of particles while the ~~filter~~ <sup>sheathless</sup> captures the remainder. Alternatively, the present invention may be configured and sized for use in peripheral vascular procedures or ~~neurovascular~~ <sup>neurovascular</sup> procedures.

15 The advantage of the ~~guidewire~~ <sup>it</sup> protective system of the present invention is that ~~the protective device~~ <sup>or apparatus</sup> behaves like an ordinary guidewire yet does not require a bulky sheath for deployment or retrieval. Unlike balloon occlusive devices that block a vessel, the ~~present invention~~ <sup>sheathless filter of the</sup> serves as a filter that allows for the continuous flow of blood, thus decreasing potential damage to ~~downstream~~ <sup>downstream</sup> tissue. Unlike other filters, the ~~present invention~~ <sup>sheathless filter of the</sup> has a variable diameter based on the extent of deployment, which further results in a range of filtration capabilities. Moreover, the flexible nature of the filter mesh conforms to vessel shape and the "soft"

multifilament polymer fibers create less damage. There are no complicated mechanical arrangements or valve systems internal or external to the ~~guidewire~~ protective system <sup>or apparatus</sup>

### BRIEF DESCRIPTION OF THE DRAWINGS

5 FIG. 1 is a ~~perspective~~ <sup>side</sup> view of the ~~present invention~~ <sup>protective system or apparatus</sup> prior to expansion of the ~~filter~~ <sup>sheathless</sup> ~~assembly~~.

FIG. 2 is a ~~perspective~~ <sup>side</sup> view of the ~~present invention~~ <sup>protective system or apparatus</sup> after expansion of the ~~filter~~ <sup>sheathless</sup> ~~assembly~~.

FIG. 3 is a close-up ~~perspective~~ <sup>side</sup> view of the ~~filter assembly~~ <sup>a portion of protective system or apparatus featuring the sheathless</sup> of the ~~present invention~~ prior

10 to expansion. FIG. 4 is a close-up ~~perspective~~ <sup>side</sup> view of the ~~filter assembly~~ <sup>a portion of protective system or apparatus featuring the sheathless</sup> of the ~~present invention~~ partially expanded.

FIG. 5 is a close-up ~~perspective~~ <sup>side</sup> view of the ~~filter assembly~~ <sup>a portion of protective system or apparatus featuring the sheathless</sup> of the ~~present invention~~ at full operational expansion.

15 FIG. 6 is a ~~close-up perspective~~ <sup>detail braided and filter mesh</sup> view of the ~~wire mesh~~ <sup>sheathless</sup> framework of the ~~filter assembly~~ of the ~~present invention~~.

FIG. 7 is a ~~perspective~~ <sup>side</sup> view of the ~~present invention~~ <sup>protective system or apparatus</sup> with a clamp attached <sup>to the control cable</sup>.

FIG. 8 is a side view of another embodiment of the ~~present invention~~ <sup>protective system or apparatus</sup>.

FIGS. 9A, 9B and 9C are detailed cross-sectional views of the ~~filter~~ <sup>sheathless</sup> of the embodiment

20 shown in FIG. 8.

FIG. 10 is a detailed ~~cross-sectional~~ <sup>side</sup> view of the ~~distal~~ <sup>flexible guidewire tip</sup> tip of the embodiment shown in

FIG. 8.

FIG. 11 is a <sup>magnified</sup> ~~FIG. 11~~ view of a section of the <sup>filter</sup> ~~mesh~~ of one embodiment of the <sup>sheathless</sup> ~~protective~~ filter.

FIG. 12 is a detailed view of the proximal attachment of the <sup>sheathless</sup> ~~protective~~ filter to the tubular guidewire.

5 ~~FIGS. 13 and 14 are cross-sectional views of pieces of a clamp arrangement for use with one embodiment of the present invention.~~

<sup>FIGS. 13 and 14</sup> ~~FIGS. 15 and 16 are cross sectional views of an interference feature for use with one embodiment of the present invention.~~

## 10 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is a <sup>or apparatus</sup> ~~guidewire~~ protective system <sup>protective system or apparatus</sup> for use in vascular procedures. The ~~invention~~ includes a tubular guidewire having a proximal end, a distal end, and a lumen <sup>FIG. 9</sup> ~~FIG. 9~~; a control cable, having a proximal end and a distal end, ~~is~~ disposed in the lumen of the tubular guidewire <sup>FIG. 9 and 9</sup> ~~FIG. 9 and 9~~.

15 <sup>The sheathless filter</sup> ~~A sheathless protective filter~~ distally coupled to the control cable and proximally coupled to the tubular guidewire expands in response to the displacement of the control cable relative to the <sup>tubular</sup> ~~guidewire~~ such that the <sup>sheathless proximal exterior primary filter</sup> ~~filter~~ presents at least a <sup>convex</sup> ~~convex~~ surface to the flow of blood in a blood vessel. In one embodiment, the sheathless ~~protective~~ filter has a distal interior <sup>concave surface</sup> ~~face~~ which provides a secondary <sup>filter</sup> ~~filtering~~ surface. The distal interior face presents a <sup>concave</sup> ~~concave~~ surface to the <sup>blood</sup> ~~flow~~ of blood within a vessel.

20 The <sup>protective system or</sup> ~~guidewire protection~~ apparatus is preferably provided with a mechanism <sup>or means</sup> ~~for~~ resisting displacement of the control cable relative to the tubular guidewire. In one embodiment, ~~FIG. 12~~

a short tube intermediate  
~~Intermediate shaft~~ is disposed ~~between~~ the tubular guidewire and ~~the~~ control cable at the proximal  
of the tubular guidewire end. The ~~Intermediate shaft~~ short tube is crimped to resist movement of the control cable. When the  
control cable is adjusted, it thus remains in place due to the resistance created by the ~~Intermediate~~ short tube  
~~shaft~~. In another embodiment, the control cable contains a stop so as to limit displacement. In a  
5 further embodiment, a clamping mechanism is used to selectively clamp the control cable ~~from~~ to resist displacement  
the guidewire. Alternatively, ~~a feature of~~ the control cable may be ~~designed~~ equipped with structure to provide an  
interference fit with ~~an~~ the interior of the lumen of the tubular guidewire.

The sheathless ~~exclusive~~ filter is preferably comprised of ~~a~~ wire ~~mesh~~ elements that form a  
tubular braided framework over which other members are woven to create the filter ~~surface~~ mesh. In  
10 one embodiment, the other ~~fibers~~ members are multifilament polymer fibers. In an alternate embodiment,  
the other ~~fibers~~ members are Nitinol wires of different diameters. The wire ~~used~~ elements for the framework  
are biocompatible and ~~have~~ material properties consistent with that needed to create a braided  
structure. For example, Nitinol wire elements could be used in this application. In an alternate  
embodiment, the multifilament polymer fibers that create the filter ~~surface~~ mesh could be woven into a  
15 fabric and then attached to the wire ~~mesh~~ braided framework.

To allow deployment of the ~~guidewire protection system~~ sheathless filter, the control cable is longer and  
has a smaller inner diameter of the tubular guidewire. Preferably, the outer diameter of the  
tubular guidewire is 0.018 inches or less. In addition, the proximal end of the tubular guidewire will be free of  
any mechanical connections and obstructions so as to enable the tubular guidewire to  
20 guidewire while the sheathless filter is deployed.

The present invention provides a method of preventing plaque, thrombus or ~~other~~  
grumous material and debris from flowing downstream during vascular procedures. The method

includes guiding a tubular guidewire into a blood vessel. A protective filter is then positioned located at the proximate distal end of the tubular is positioned and distal to the region of the blood vessel to be treated.

A control cable coaxially disposed within the tubular and affixed to the sheathless filter is displaced, thus expanding the sheathless protective filter to a deployed state which spans the diameter of the blood vessel. The tubular

5 guidewire is clamped at the proximal end so as to prevent unwanted further displacement of the control cable during the vascular procedure. In a preferred embodiment, the tubular guidewire has an outer diameter of up to 0.018 inches and is made of Nitinol or comparable material.

A catheter is introduced over the proximal end of the tubular is advanced to the region of the blood vessel to be treated. A vascular procedure is then performed in the area using

10 the catheter. The present invention may be incorporated with a vascular procedure such as an asymmetric water jet atherectomy wherein a jet directs a working fluid at a velocity sufficient to generate a stagnation pressure for removal of an ablated deposit debris. The catheter is also used to remove material captured by the proximal exterior primary filter surface sheathless of the filter. The control cable is

then released from the crimped guidewire thus contracting the sheathless filter. The tubular guidewire with sheathless filter is then guided out of the blood vessel.

15 In the preferred method, the sheathless protective filter is comprised of a braided framework over which other members are co-braided to create a barrier to particles. The wire mesh is attached to the distal end of the control cable and proximate end of the tubular braided framework. The wire mesh and other co-braided members are selectively spaced so that particles are captured. In one embodiment, the other members are multifilament polymer fibers. In an alternate embodiment, the other members are Nitinol wires of different diameters. Preferably, the co-braided other members braided framework are spaced to capture particles of at least 250 microns and more preferably down to 100-150 microns. In the

alternative, the multifilament polymer fibers are woven into a fabric and then attached to the ~~wire~~ <sup>braided framework</sup>.  
~~mesh~~ <sup>sheathless</sup>. Before deployment, the ~~exclusion~~ <sup>braided framework</sup> filter has a closed position in which the ~~wire mesh~~ <sup>braided framework</sup> and  
<sup>or other members</sup> multifilament polymer fibers are disposed generally parallel to the control cable so that the  
<sup>sheathless filter</sup> ~~present invention~~ <sup>blood</sup> can be inserted into a vessel.

5 The present invention is also a system <sup>or apparatus</sup> for filtering emboli from the blood of a patient  
generally coincident to a vascular procedure. The system <sup>or apparatus</sup> includes <sup>blood vessel</sup> lumen opening means, debris  
<sup>of a blood vessel</sup> filtering means, and emboli evacuation means. To open the lumen <sup>is used which has</sup> a catheter ~~with~~ <sup>fluid</sup> a distal end  
having one or more orifices from which a working fluid, such as saline under high pressure, is  
directed in the form of a fluid jet at a deposit within the blood vessel. The jet impacts the deposit  
10 longitudinally so as not to damage the blood vessel. The impact dislodges the deposit and  
creates a plurality of debris particles.

<sup>blood vessel</sup> The <sup>or apparatus</sup> lumen opening means further includes a tubular member containing a hypo tube.  
Preferably, the tubular member is used as an evacuation lumen. The ~~lumen~~ <sup>hypotube</sup> further includes one  
<sup>fluid</sup> or more high velocity jets directed to strike a portion of the tubular member. The high velocity <sup>fluid</sup>  
15 jet <sup>fluid</sup> creates a localized low pressure region which draws the debris particles to the jets and  
subsequently down the exhaust lumen.

<sup>the sheathless</sup> The debris filtering means includes <sup>the tubular</sup> a tube-shaped <sup>sheathless</sup> filter which is advanced distally of the  
deposit by <sup>braided</sup> a guidewire. The ~~tube-shaped~~ <sup>braided</sup> filter is comprised of a wire ~~mesh~~ <sup>braided</sup> framework over  
which a plurality of strands are co-braided. The wire ~~mesh~~ <sup>braided</sup> framework is radially deployed. The  
<sup>braided wire framework</sup> ~~tube-shaped filter~~ <sup>its</sup> is fixed at <sup>tubular</sup> a proximal end to the guidewire and the wire ~~mesh~~ <sup>braided</sup> framework is  
20 <sup>its</sup> fixed at <sup>wire</sup> the distal end to the control cable. In a non-deployed state, the individual elements of  
<sup>braided</sup> the wire ~~mesh~~ <sup>control cable and the tubular</sup> framework lie generally parallel to the guidewire.

The ~~tube-shaped~~ <sup>sheathless</sup> filter can be selectively deployed so as to radially expand to ~~encompass~~ <sup>span</sup>

the diameter of the blood vessel. At a lower deployment limit, no fluid is able to pass through the filter. In a first embodiment, the lower ~~limit~~ <sup>deployment</sup> for the ~~filter~~ <sup>sheathless</sup> would be 3 mm. Likewise, the ~~tubular~~ <sup>sheathless</sup> filter has an upper ~~limit~~ <sup>deployment</sup> based on the unoccupied distance between any two of the

5 strands. This unoccupied distance is defined as a pore size. In a first embodiment, the maximum pore size is 0.010 inch in each direction of the opening so that the ~~tube-shaped~~ <sup>sheathless</sup> filter would be able to capture particles of 250 microns or greater. Alternatively, the maximum pore size is 0.005 inches <sup>sheathless</sup> so that the ~~filter~~ <sup>sheathless</sup> is able to capture particles of 100-150 microns or greater. In an alternate embodiment, the multifilament fibers are woven into a fabric prior to attaching them to the ~~wire mesh~~ <sup>braided</sup> framework.

In one embodiment, the debris capturing means includes two filtering surfaces. First, a proximal ~~convex face~~ <sup>exterior filter surface</sup> of the ~~tube-shaped~~ <sup>sheathless</sup> filter blocks the passage of particles immediately downstream of the vascular procedure. A second debris capturing means includes an interior concave filter ~~face~~ <sup>surface</sup> at the distal end of the ~~tube-shaped~~ <sup>sheathless</sup> filter.

15 The outer diameter of the ~~tube-shaped~~ <sup>sheathless</sup> filter is smaller than the inner diameter of the blood vessel prior to deployment. In a first embodiment, it is envisioned that the ~~tube-shaped~~ <sup>sheathless</sup> filter will have an outer diameter of no more than ~~0.046 inches~~ <sup>0.038 inch</sup> prior to deployment.

In operation, it is envisioned that emboli evacuation would include removing the displaced emboli from the proximal ~~convex face~~ <sup>exterior filter surface</sup> of the ~~tube-shaped~~ <sup>sheathless</sup> filter through the use of the evacuation lumen. The evacuation lumen is attached to a vacuum pump which provides suction at the distal end. In addition, the evacuation lumen may be driven by the fluid jets which create a stagnation pressure upon striking the mouth of the evacuation lumen. Emboli evacuation is

filter surface sheathless  
further accomplished due to the interior concave face at the distal end of the tube-faced filter  
catching emboli that are not trapped by the proximal convex face. The filter is contracted and  
removed from the body upon completion of the procedure. The trapped emboli are maintained  
within the filter body during the removal procedure.

5 Referring now to FIG. 1-2, the overall operation of a structure end or apparatus  
guidewire-filter protective system

20 in accordance with the present invention will be described. The guidewire-filter protective  
system 20 in accordance with one embodiment includes a tubular assembly 30, protective  
filter assembly 50, and a control cable 38.

9 sheathless  
The guidewire assembly 30 is a tubular member that includes a proximal end 32 and a  
10 distal end 34. As used in the present invention, the terms proximal and distal will be used  
with reference to an operator of the device, such that the end 34 of the tubular  
assembly 30, for example, is the portion first inserted into a blood vessel, and the proximal  
end 32 is the portion which remains exterior to the patient and is therefore closer to the operator of the device.

tubular  
The guidewire assembly 30 receives the  
15 optional intermediate shaft 40. The guidewire 36 is a tubular member having a proximal end 32,  
which remains exterior to the patient, and a distal end 34 which in operation is proximate a  
vessel of the patient.

The control cable 38 is a wire having a proximal end 48 and a distal end 49 slidably  
disposed within the lumen of guidewire 30. The control cable 38 extends proximally and distally  
20 beyond the respective ends of the tubular guidewire 30. The total length of control cable 38 is longer than  
guidewire 30 to provide for the filter assembly 50 at the distal end 34 and a gripping region 46 at



the proximal end 32. Exact length for the respective elements <sup>are</sup> determined by the required path to reach the occlusive site within the patient.

In a preferred embodiment, a flexible guidewire tip 60 is positioned in a sleeve 62 at the distal end 49 of control cable 38 to assist in deployment of the system <sup>which is attached to the control cable 38</sup> through <sup>protective or apparatus</sup> the vessel. In <sup>a blood</sup>

one embodiment, a stop <sup>travel of</sup> 66 is crimped on proximal end 48 of control cable 38 to prevent the control cable 38 from completely sliding into the lumen of guidewire <sup>tubular 30</sup> 30.

In one embodiment, the control cable 38 <sup>travel of</sup> is restricted by <sup>a short tube</sup> an intermediate shaft 40 disposed within the lumen of guidewire <sup>tubular 30</sup> 30 at the proximal end 32. The <sup>short tube</sup> intermediate shaft 40 <sup>has</sup> is a tubular member with an inner diameter slightly larger than the diameter of control cable 38 and

an outer diameter slightly smaller than the inner diameter of guidewire <sup>tubular 30</sup> 30. The <sup>short tube</sup> intermediate shaft 40 increases the resistive effect on the control cable 38 so as to maintain position relative to

guidewire <sup>tubular 30</sup> 30. <sup>The tube ordinarily is in length</sup> A relatively short intermediate shaft 40 <sup>tubular 30</sup> less than one inch <sup>short tube</sup> is used to create the resistive effect. The guidewire <sup>tubular 30</sup> 30 is crimpable relative to the intermediate shaft 40 <sup>short tube</sup> as it is

~~presumed a clamping tool 70 may also be utilized to maintain position.~~

Alternatively, the <sup>short tube</sup> intermediate shaft 40 could be eliminated and position <sup>then</sup> maintained by

crimping the proximal end 32 of the guidewire <sup>tubular 30</sup> 30 to the control cable 38, by using a torque <sup>by using a clamp,</sup> device, by the interaction of a <sup>projection</sup> feature on the control cable 38 with the interior diameter <sup>surface</sup> of the

guidewire <sup>tubular 30</sup> 30, or simply by maintaining relative position manually. Although the diameter of the control cable 38 could be of any size consistent with effective use of <sup>the tubular 30</sup> guidewire 30, it will be

understood that the larger diameter creates a resistive effect on the guidewire <sup>tubular 30</sup> 30, or <sup>the tubular 30</sup> intermediate shaft 40, so as to maintain position relative to <sup>short tube</sup> guidewire <sup>tubular 30</sup> 30 when force is removed.

sheathless

A protective filter assembly 50 having a proximal end 52 and a distal end 54 is located at the distal end 34 of guidewire assembly 30. The protective filter assembly 50 is preferably

sheathless

tubular

comprised of a wire mesh framework 56 over which a plurality of multifilament polymer fibers

braided

to form a filter mesh 58

braided

filter 58

are braided. Alternatively, the wire mesh framework 56 may support a mesh of other fibers

5 or wires, such as Nitinol mesh wires 58 as shown in FIG. 11. The proximal end 52 of

the sheathless

34

tubular

30

exclusive filter assembly 50 is laser-welded to the distal end 44 of guidewire 30 as shown in FIG.

the sheathless

12, for example, while the distal end 54 of exclusive filter assembly 50 is laser-welded to the

(see FIGS. 4 and 5)

distal end 49 of control cable 38. In one embodiment, a control cable stop 68 is disposed on

the sheathless

control cable 38, between the proximal end 52 and distal end 54 of filter assembly 50, so as to

10 limit the travel of control cable 38. Exact location of the stop 68 is determined by the filter

braided

spacing created upon radial expansion of the wire mesh framework 56 as compared to the

particle size to be filtered.

braided

The individual wire elements 64 of wire mesh framework 56 are disposed parallel to

tubular

30 and control cable 38

guidewire 30 at the point of attachment so as to present a minimal crossing profile. Individual

1

5

braided

framework

15 monofilament polymer fibers 58 are co-braided about the wire mesh 56 to increase cross-section

wire elements

other

coverage without the stiffness associated with the wires 64. Alternatively, the members 58 may

strands or

wire elements 64

be comprised of smaller diameter wires that exhibit more flexibility than the wires associated

braided wire

56 may be used

sheathless

with the framework 56. In one embodiment, the filter assembly 50 may be coated with a

hemocompatible compound to minimize shear activation of platelets.

20 During interventional procedures involving carotid arteries and saphenous vein bypass

grafts, embolic particles may be liberated causing adverse complications if preventive means are

not in place. In a preferred embodiment, as illustrated in FIGS. 1-6, the guidewire filter

~~occlusion~~ <sup>protective or apparatus</sup> system 20 provides embolic protection. In one embodiment, the tubular guidewire ~~30~~ <sup>30</sup>  
 is formed of a <sup>tube</sup> Nitinol ~~shaft~~ having an outer diameter of 0.014 inches, an inner diameter of 0.010  
 inches, and a length of 180 cm. In an alternate embodiment as shown in FIG. 8-10, the tubular  
 guidewire ~~30~~ <sup>30</sup> is formed of a braided polyimide tube having an outer diameter of 0.015 inches, an  
 5 inner diameter of 0.011 inches, and a length of 180 cm, such as available from MedSource  
 Technologies, Trenton, Georgia. In one embodiment, the control cable 38 is formed of a <sup>wire</sup> Nitinol  
~~rod~~ having a diameter of 0.008 inches and a length of 190 cm. In an alternate embodiment, the  
 control cable 38 is formed of a Teflon<sup>®</sup> coated stainless steel <sup>wire</sup> ~~rod~~ having a diameter of 0.095  
 inches. The control cable ~~core~~ 38 is disposed coaxially with the <sup>tubular</sup> guidewire ~~30~~ <sup>30</sup>. Although the  
 10 length of the <sup>tubular</sup> guidewire ~~30~~ <sup>30</sup> could be any length, it will be understood that it will be shorter than  
 the length of control cable 38. In a first embodiment, the control cable 38 will be at a minimum  
 of 10 cm longer so as to provide for the attachment of the <sup>sheathless</sup> filter assembly 50 at the distal <sup>end</sup> ~~portion~~  
 34 and a gripping <sup>region</sup> ~~area~~ 46 at the proximal <sup>end</sup> ~~portion~~ 32. In one embodiment, <sup>short tube</sup> intermediate shaft 40,  
 is also preferably made of <sup>wire</sup> Nitinol with a length of 0.05 inches.  
 15 As shown in FIG. 1, the <sup>flexible</sup> guidewire tip 60 is disposed at the distal <sup>end</sup> ~~portion~~ 34 of the <sup>49 of the control cable 38</sup> ~~guidewire~~  
~~assembly~~ <sup>flexible</sup> 30. The guidewire tip 60 is preferably a platinum coil with a stainless steel core <sup>61</sup> having  
 a maximum diameter of 0.018 inches and a length of 1.0 inch. Attachment of guidewire tip 60 is  
 accomplished in one embodiment by a stainless steel sleeve 62 that is laser-welded to control  
 cable ~~core~~ 38. A crimp is applied to the sleeve 62 to hold the tip 60 in place. FIG. 10 shows an  
 20 alternate embodiment <sup>flexible</sup> ~~of the construction of the~~ guidewire tip ~~60~~ <sup>60a wherein</sup> ~~where~~ the <sup>flexible</sup> tip core <sup>63</sup> is fabricated  
 as part of the control <sup>cable 38</sup> ~~rod~~.

In one embodiment, at the proximal end 48 of control cable 38, a cable stop 66 is attached. In this embodiment, cable stop 66 is 0.25 inches long with a diameter of 0.014 inches, which is equal to the diameter of guidewire 30. The cable stop 66 is crimped on control cable 38 and serves to keep the proximal end 48 of the control cable 38 from entering into the tubular guidewire 30.

~~In an alternate embodiment as shown in FIGs. 13 and 14, a hemocostatis-like clamp arrangement 80 is utilized on the proximal end 48 of guidewire assembly 20 to secure the control cable 38 relative to the tubular guidewire 30. The clamp arrangement 80 preferably consists of an actuator assembly 82 that is secured to the tubular guidewire 30 and an indicator assembly 84 that clamps onto the control cable 38 by rotation of a knob member 86 that pinches control cable 38 in a wedge structure 88. In one embodiment, the distal end of actuator assembly 82 is provided with structure 90 that attaches the actuator assembly 82 to the guidewire by a torque device, such as a collet clamp. Preferably, both the actuator assembly 82 and the indicator assembly 84 have mated threads 92 that permit the actuator assembly 82 to threadably receive the indicator assembly 84. The indicator assembly 84 preferably includes visible markings at 94 that indicate to an operator the extent of the deployed state of the filter device 50 based on the number of turns of knob 86 as the indicator assembly 84 is unscrewed and control cable 38 is displaced relative to the tubular guidewire 30. It will be understood that alternative arrangements for securing the control cable 38 and tubular guidewire 30 can be used with the indicator assembly such as a pin vise or bearing arrangement, and that a latch, ratchet or other step-wise mechanical interface could be utilized in place of the threads 82.~~

In another embodiment as shown in FIGs. 13 and 14, features an interference fit between the proximal end 48 of control cable 38 and the proximal end 32 of tubular guidewire 30 that

~~protective filter assembly~~ 50 effectively locks the ~~filter assembly~~ 50 into a minimum diameter or undeployed state

during insertion ~~of the guidewire assembly~~. This feature is particularly useful to ~~insure~~ ensure that the

~~filter assembly~~ 50 remains in as unobtrusive a state as possible during passage ~~of the distal tip 34~~ of the guidewire through lesions or tortuous areas of the vessel undergoing a vascular procedure.

5 ~~The fit is created by a projection~~ ~~Interference feature~~ 96 on the control cable 38 ~~frictionally~~ frictionally interfaces with the proximal opening of the lumen of the tubular guidewire 30 to secure the relative position between the two.

In this embodiment, the ~~interference feature~~ 96 is a frustoconical-shaped member that extends beyond the outer diameter of the control cable 38. Numerous other shapes and configurations

such as a lipped configuration or a ratchet arrangement could also be used.

10 ~~Filter assembly~~ 50 is comprised of a plurality of ~~filter wires~~ 64, which form a framework 56 to support a plurality of polymer strands 58, as illustrated in FIG. 6. In a first embodiment, the polymer strands 58 are co-braided around the wire ~~mesh~~ framework 56. The ~~wires~~ 64 are made of Nitinol, a super-elastic nickel titanium alloy, which is the preferred material because it is easy

to braid and biocompatible. A plurality of laser-welds are applied at the ~~distal filter~~ end 52 and

15 ~~proximal filter~~ end 54 to hold the ends of ~~filter wire~~ 64 in position and prevent fraying. At least

two welds are performed on each wire 64 at each end so as to hold ~~the wire~~ 64 as small as possible, thus presenting a minimal profile ~~in that deployment without a sheath~~. Alternatively,

adhesive bonds or mechanical interconnections may be used in place of or in addition to welding

to secure the ~~filter assembly~~ 50. In an alternate embodiment as shown in FIGS. 11 and 12, the

20 strands 58 are also comprised of Nitinol wire having a smaller diameter (e.g., 0.008") than the

~~wires~~ 64 (e.g., 0.012").

It is expected that the radial expansion of the ~~filter assembly~~ <sup>sheathless</sup> 50 will have an upper and lower limit based on blood flow requirements at the lower limit and the ability to stop particles of an expected size at the upper limit. In a first embodiment, the lower limit of expansion would provide filtration in vessels as narrow as 3 mm. In order to filter particles of 250 microns or larger, the maximum allowable mesh gap would be 0.01 inches which corresponds to a maximum deployment diameter of 0.3 inches. In the closed position, as depicted in FIG. 3, the maximum diameter of the non-deployed ~~filter~~ <sup>sheathless</sup> 50 is 0.038 inches.

In another embodiment as shown in FIG. 8-12, the ~~filter assembly~~ <sup>sheathless 50</sup> is designed to filter particles down to a size of between 100-150 microns. The inter-mesh spacings required for such a filtration effect range between 0.004 inches and 0.008 inches as can be seen in FIG. 11, for example. In this embodiment, the expansion size of the ~~filter assembly~~ <sup>sheathless</sup> 50 in a deployed state is selected among a plurality of sizes (e.g., 2-4 mm diameter vessels, 4-6 mm diameter vessels, 6-8 mm diameter vessels) to control the filtration effect of a given sized ~~filter~~ <sup>sheathless 50</sup> by providing a known range of diameters in the deployed state for which the inter-mesh spacings necessary to achieve the desired filtration effect can then be chosen. In tests with the ~~filter assembly~~ <sup>sheathless 50</sup> of the

present invention deployed within a 6.2 mm acrylic tube, polymer particles of ~~known~~ <sup>known</sup> size were introduced into a fluid flow simulating blood to determine the effectiveness of the ~~filter~~ <sup>sheathless</sup> 50

~~assembly~~. When particles of a size of 200 microns were used in this test, 100% of the particles were trapped by the ~~first~~ <sup>primary surface</sup> convex ~~filter~~ <sup>sheathless 50</sup> of the ~~filter assembly~~.

When the particle size was reduced to 157 microns, 50% of the particles were trapped by the ~~first~~ <sup>primary surface</sup> convex ~~filter~~ <sup>sheathless 50</sup>, 40% were trapped by the ~~second~~ <sup>secondary surface</sup> concave ~~filter~~ <sup>sheathless filter 50</sup> and approximately 10% of the particles flowed through the ~~protective~~

~~device~~. It will be seen that the sizes of the inter-spacing pores may be adjusted if protection for

sheathless filter 50  
smaller size particles is desired to improve the effectiveness of the protective device for particles at those smaller sizes while potentially reducing the flow of blood due to the use of the smaller size pores.

sheathless (see Figs. 4 and 5)  
To limit radial expansion of filter assembly 50, in one embodiment control cable stop 68

5 is coaxially disposed on control cable 38 between the proximal and distal ends of filter assembly 52 and 54 sheathless

50. Cable stop 68 is a stainless steel tube crimped on to control cable 38 with an outer diameter

tubular 30 of 0.012 inches which stops the control cable 38 from traveling into the lumen of guidewire 54.

fibers, strands or of the filter mesh the wire elements 64 of the braided wire framework 56  
The wires 58 and strands 60 lie generally parallel to control cable 38 when inserted into a vessel. As control cable 38 is proximally extended, distal end 52 is drawn toward

10 stationary proximal end 54. Initial displacement, as depicted in FIG. 4, for example,

sheathless 50 expands creates a narrow tube as the filter wires expand radially in an elastic manner to form a thin tube.

As the control cable 38 is further displaced, the filter wires 58 continue their radial expansion, as depicted in FIG. 5, until reaching stop 62 or filling the vessel takes place

sheathless It will be understood that the weave of filter assembly 50 may be varied in a number of

15 ways including: changing the number of filaments per strand of polymer fiber; changing the

changing the diameter of the polymer filaments; changing the number of Nitinol strands which form the wire framework 56 changing the mesh skeleton; changing the diameter of Nitinol strands; and changing the design of the tubular

weave. A further advantage to this design is the "softness" created by the polymer fibers as they

interact with the blood vessel. Varying the Nitinol strands has a direct effect on the stiffness of

sheathless 50 number of wire elements  
20 the filter and the "softness." However, the Nitinol strand number must be sufficient to

adequately constrain the multifilament polymer fibers. Clearly, the options described above may

*sheathless 50*  
be used to tighten or relax the weave of the filter. Furthermore, the options may be combined to achieve comparable results.

In practice, medical personnel gain access to the blood vessel lumen through which the *protective system or apparatus* *or apparatus* ~~guidewire assembly~~ 20 will travel. The ~~guidewire-filter~~ protective system 20 is removed from biocompatible packaging. *Flexible guidewire* *blood vessel* ~~Guidewire~~ tip 60 is inserted into the lumen and is manipulated to a point beyond the vessel occlusion. The control cable 38 is drawn *proximally* ~~distally~~ from the tubular guidewire *30* *sheathless* *blood vessel* ~~30~~ so as to radially deploy the filter 50 within the lumen. A rapid exchange device, such as a stent catheter or thrombectomy device, is then deployed on the tubular guidewire *30* with the *sheathless* ~~filter assembly~~ 50 in a deployed state. As illustrated in FIG. 7, a clamp 70 is then applied to the *control cable 38* *sheathless* ~~guidewire assembly~~ 20 to maintain the deployed position of the filter 50 until completion of the procedure.

In a preferred embodiment of the present invention, the ~~guidewire~~ *or apparatus* protective system 20 is utilized *in* ~~as the guidewire for~~ an atherectomy or thrombectomy procedure of the type described in U.S. Patents Nos. 5,370,609 or 5,496,267, the disclosure of each of which is hereby incorporated by reference. In each of these embodiments, the ~~guidewire~~ *or apparatus* protective system 20 is introduced into the patient, the *sheathless* filter 50 is radially deployed, and then the atherectomy or thrombectomy catheter arrangement is slid over the proximal end 32 of the *tubular* ~~guidewire assembly~~ 30 and advanced until it is proximate and proximal to the location of the *sheathless* ~~filter assembly~~ 50. Unlike other occlusive methods, the time period of the procedure is not constrained by concern over blockage of the *blood* vessel. The radial expansion of *sheathless* filter ~~assembly~~ 50 allows for the continual flow of blood through the spacing between individual *strands of the filter mesh* *sheathless* ~~polymer fibers~~ 58. Thus, ~~filter assembly~~ 50



50 is preferable where ischemia is intolerable or further blood cessation would be irreparably damaging.

Preferably, an evacuation of any debris ~~for other plaque material~~ dislodged in the therapy is accomplished by the evacuation lumen incorporated within the catheter assembly of the above-

5 referenced patents. However, should debris ~~for plaque~~ escape the evacuation lumen, the <sup>proximal exterior</sup> convex <sup>filter surface sheathless</sup> ~~proximal face 72~~ of the filter ~~assembly~~ 50 provides the primary <sup>filtering surface</sup> ~~means~~ for trapping this detritus. <sup>distal interior</sup> ~~The concave interior face 74~~ of the filter ~~assembly~~ 50 provides a <sup>secondary</sup> ~~second~~ filtering surface. <sup>sheathless 50</sup> Additionally, a sponge could be compressed to fit within the collapsed filter ~~assembly~~. Upon deployment, the sponge would provide a third level of filtering. After completion of the <sup>sheathless 50</sup> procedure, the filter ~~assembly~~ is returned to an undeployed state and the <sup>tubular</sup> ~~guidewire assembly 20~~ <sup>30</sup> ~~and filter assembly~~ 50 are retracted.

The present invention may be embodied in other specific forms without departing from the essential attributes thereof; therefore, the illustrated embodiments should be considered in all respects as illustrative and not restrictive, reference being made to the appended claims rather  
15 than to the foregoing description to indicate the scope of the invention.

ABSTRACT OF THE DISCLOSURE

a tubular guidewire, a control cable slidable within the tubular guidewire, and

protective or apparatus

A ~~guidewire protection~~ system for use in vascular procedures includes a sheathless

~~protective filter proximate a distal end of a tubular guidewire assembly. In one embodiment, a~~

~~control cable disposed within the guidewire~~ is attached to a distal end of the filter ~~while~~ the

5 ~~tubular~~ guidewire is attached to a proximal end of the filter. Selective displacement of the control cable

radially expands the filter to create a ~~tube-shaped filter having a~~ convex primary filter surface

that is positionable downstream from a site of a vascular procedure. ~~In this embodiment, the~~

~~filter also presents a concave secondary filter surface. Preferably, the sheathless protective filter~~

is constructed of a braided wire ~~mesh~~ over which polymer fibers are woven to create a softer

10 filter surface.